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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appln. No. : 10/007,812
Applicant : ROBERT S. SUPINSKI
Filed : November 8, 2001
Title : PATELLA REPLACEMENT APPARATUS

Group Art Unit : 3732
Examiner : David C. Comstock

Docket No. : 011072

LETTER

Pittsburgh, Pennsylvania 15219

December 28, 2006

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Notice dated December 1, 2006, enclosed is a second corrected brief on appeal. The brief has been corrected to add "to be Reviewed on Appeal" after the heading "Grounds of Rejection." Also, the Appendices, Evidence Appendix and Related Proceedings Appendix, have been placed on separate pages.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

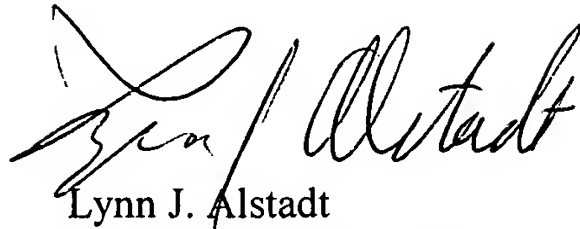
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

on this 28th day of December, 2006.


Buchanan Ingersoll & Rooney, PC

Acceptance of this corrected brief is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lynn J. Alstadt". The signature is fluid and cursive, with the first name "Lynn" and last name "Alstadt" clearly distinguishable.

Lynn J. Alstadt

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SECOND CORRECTED BRIEF ON APPEAL

Real Party in Interest

The real party in interest is applicant, Dr. Robert S. Supinski.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims 1 through 26 are pending in the application. In an Office Action dated February 23, 2004, Examiner David A. Bonderer allowed all claims. Then on June 16, 2005, a different Examiner, David C. Comstock, withdrew the allowance and rejected all claims. Examiner Comstock refused a Request for Reconsideration and finally rejected all claims on December 14, 2005. The appeal followed.

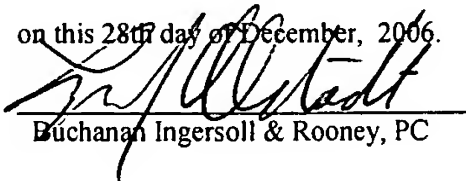
Status of Amendments

No amendments were filed subsequent to the Office Action dated December 4, 2005, from which this appeal is taken.

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on this 28th day of December, 2006.


Buchanan Ingersoll & Rooney, PC

Summary of and Claimed Subject Matter

The claims define a patella replacement device for use in repairing or replacing the destroyed natural patella of a patient. Three embodiments are shown in the drawings. Figures 1 through 4 show the first embodiment, Figures 5 through 7 show the second embodiment and Figures 8 and 9 show the third embodiment. The claimed patella has two generally hemispherical members identified by reference numbers 11 and 12 in Figure 1, reference numbers 21 and 22 in Figure 5 and reference numbers 31 and 32 in Figure 8. (p. 4, line 20 - p. 5, line 1).^{*} Claims 1-21 require that one of the two members (component 12 in Figure 1) be fabricated from a porous material and be attached to the other member (component 11) during implantation. (p. 5, lines 6-8; p. 6, lines 1-2). The second member need not have a porous surface. (p. 5, lines 6-7). Both members are fabricated from biocompatible materials. (p. 5, lines 3-5). One member preferably is a plastic and the other member preferably is metal. (p. 5, lines 5-6). The porous nature of the first member allows biological fixation of the device to the patella region of the patient. (p. 5, lines 19-20). The claims also require that the first member have a rounded fixation surface for implantation within the patella region of a patient and a relatively flat surface opposite the rounded surface. (p. 4, line 22 through p. 5 line 1). The second member has a top rounded surface and an opposing surface. (p. 5, lines 2-3). At least one projection (part 17 in Figure 2) extends from that surface and fits into a mating aperture (holes 18 in Figure 3) in the flat surface of the first member to enable the first member to couple to the second member. (p.5, lines 13-18; p. 9 lines 7-9).

One embodiment defined by independent claim 15 also has an annular ring (item 24 in Figure 5) having a greater diameter than the diameters of the first and second members

^{*} All references to pages and line numbers (i.e., p. ____, lines ____) refer to the specification.

(components 21 and 22 in Figure 5) and suture holes about the periphery of the ring. (p. 7 lines 12-18). This ring has a flange that surrounds the first member. (p. 7 lines 12-14).

An alternative embodiment of the patella replacement device shown in Figures 8 and 9 is defined by independent claim 22. (p. 9, line 7 through p. 10, line 4). That embodiment 30 has two members 31, 32 as in the other embodiments and also has a porous coating containing at least one bone growth material. (p. 9 lines 4-22).

None of the claims contain a means plus function clause.

Grounds of Rejection to be Reviewed on Appeal

The Examiner rejected claims 1-3, 5, 7-10, 12, 14, 15, 17, 19-22 and 24-26 under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,019,104 to Whiteside et al.

Claims 4, 11, 13, 16, 18 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Whiteside et al.

No ground of rejection is stated as to claim 6 in the Office Action from which this appeal is taken.

ARGUMENT

The Rejection Constitutes an Improper Comment on Validity of an Issued Patent.

Claims 1 to 21 on appeal were copied from U.S. Patent No. 6,146,432 to Cohen et al. which issued on November 14, 2000. United States Patent No. 5,019,104 to Whiteside et al. was among the references cited by the Examiner in the prosecution of that application. The Examiners handling the '432 patent determined that these claims were patentable over the Whiteside reference.

It is respectfully submitted that it is improper for the Examiner to reject the claims copied from the Cohen patent, particularly when the Whiteside reference was considered by the Office in granting the Cohen patent.

As set forth in M.P.E.P. §1701:

Every patent is presumed to be valid. 35 U.S.C. 282, first sentence. Public policy demands that every employee of the United States Patent and Trademark Office (USPTO) refuse to express to any person any opinion as to the validity or invalidity of, or the patentability or unpatentability of any claim in any U.S. patent, except to the extent necessary to carry out

- (A) an examination of a reissue application of the patent,
- (B) a reexamination proceeding to reexamine the patent, or
- (C) an interference involving the patent.

Clearly, none of the above-mentioned exceptions apply in this instance. There is no reissue or reexamination proceeding. An interference has yet to be declared. The rejection of the language appearing in the patented claims is occurring during *ex parte* prosecution.

The grounds for rejection quite clearly express the opinion that the claims contained in United States Patent No. 6,146,432 are unpatentable and thus are invalid. It is respectfully submitted that this rejection is inappropriate during *ex parte* prosecution. When interference is declared, the issues of patentability of these claims can then be openly explored. However, raising it here on *ex parte* prosecution is clearly premature and inappropriate.

The claims on appeal had been allowed over this reference by Examiner Bonderer who originally examined this application. That was the proper course of action.

Claims 1-3, 5, 7-10, 12, 14, 15, 17, 19-22 and 24-26
are Patentable Under Section 102 Over Whiteside.

For an invention to be anticipated and properly rejected under Section 102 every element of the claim must be found in a single cited reference. The Whiteside reference does not disclose every element of any of the pending claims.

Claims 1, 8, 15 and 22 are the only independent claims on appeal. All the claims are directed to a patella replacement device having a first member and a second member. In the most recent Office Action the Examiner has identified metallic backing portion 12 in Whiteside as corresponding to the first member in applicant's claims and polymeric surface layer 15 as corresponding to the second member in applicant's claims.

Claims 1 and 8 both require

"a first member fabricated from a porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with said porous metal allowing biological fixation to said patella region of said patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein,"

This element of the claims is not disclosed by Whiteside et al.

Whiteside discloses a patellar prosthesis formed from a rigid, preferably metallic backing portion 12 having "integrally formed securing pegs 13 which are provided to secure the prosthesis to the posterior side a resected patella." Col. 2, lines 16-21. At column 2, lines 22-24 the reference says "the anterior surface of metallic attachment portion 12 can be provided with a porous layer such as sintered metal microbeads 14 to allow for tissue growth." This statement tells us that the metallic attachment portion 12 is not porous and that the metallic portion 12 does not allow for tissue growth. If portion 12 were porous it would not be necessary to provide porous layer 14. The Whiteside patella prosthesis also has a polymeric surface layer 15 which is pressure molded onto the attachment portion 12 fully covering the upper covered surface of the attachment layer.

Whiteside's backing member 12 does not meet the "first member" limitation because backing member 12 is not fabricated from a porous material, is not porous and does not allow biological fixation to the patella region. Whiteside specifically teaches that a porous layer 14 is

applied to member 12 to allow for tissue growth. So, one skilled in the art reading Whiteside would understand that member 12 is not porous. The reference says that the porous layer 14 is applied "to allow for tissue ingrowth." (Col. 2, line 24). From that statement one skilled in the art would conclude that the backing member 12 does not allow for tissue growth and hence does not allow for biological fixation to the patella region as required by applicant's claims.

Moreover, Whiteside also says that pegs 13 are provided to secure the prosthesis to the posterior side of a resected patella. Without those pegs the Whiteside device could not be fixed to the patella region of the patient and would not be operable. In applicant's device the porous structure allows "bone and tissue to grow into the component and anchor the prosthesis." Specification page 9, lines 2-3. This biological fixation is quite different from the mechanical attachment using pegs that is taught by Whiteside. These differences in structure, use and function of the first member in applicant's claims and the backing element 12 in the reference are such that claim 1 and 8 are neither anticipated by nor obvious from the Whiteside reference.

In the Final Office Action from which this appeal is taken the Examiner responded to this argument saying:

It is first noted that the backing member comprises the porous layer and is therefore porous when taken as a whole. Applicant cannot separate the components and then claim that one of the resultant portions does not possess the requisite characteristics that were provided by the other. The porous layer forms part of the backing member, and in fact, it is this layer that allows the member to be considered porous."

The Examiner's argument ignores the claim language. The claims require "a first member fabricated from a porous metal and having a rounded fixation surface . . . said first member having a relatively flat surface opposite the rounded surface." A non-porous structure having a porous layer is not a "member fabricated from a porous metal." The porous layer is fabricated from a porous metal, but that layer does not have a rounded fixation surface and a flat

surface opposite the rounded surface. The microbeads 14 which form porous portions of the Whiteside device can be seen in Figures 1 and 2 as each having two flat surfaces. Moreover, the microbeads are shown as covering only a portion of the non-porous metal backing element 12.

The essence of the Examiner's position is that applying a layer of microbeads to portions of one surface of a non-porous metal backing element meets the claim requirement of a member "fabricated from a porous metal." That position is clearly wrong. "Fabricated," according to Webster means, "manufactured" or "construct[ed] from." A "layer" is "one thickness, course or fold laid or laying over or under another" layer or structure. Webster's New Collegiate Dictionary. Applying a porous layer to a non-porous structure does not make that structure fabricated from a porous material.

The error of the Examiner's reasoning is confirmed by the actions of three patent Examiner's who said the claims on appeal are patentable over Whiteside. Examiner Bonderer allowed these claims in this application. Assistant Examiner Suzette J. Jackson acting with Primary Examiner David H. Willse allowed the same claims over Whiteside in the application which issued as United States Patent No. 6,146,423 to Cohen et al.

Claim 15 requires the same first and second members that are required by claims 1 and 8. In addition to requiring a first member and a second member, claim 15 further requires:

"an annular ring secured about said first member, said ring having a central aperture, an extending flange portion surrounding said first member and a plurality of apertures about a periphery thereof; and . . . a peripheral gap is formed between said first and second members . . . "

The Whiteside device does not meet this requirement. There is no gap between backing portion 12 and surface portion 15. There is also no structure separate from backing portion 12 and surface layer 15. Hence, only a first member and a second member are present in the Whiteside prosthesis. In rejecting claim 15 the Examiner states, "The reduced width outer peripheral

portion of the device can be characterized as an integral ring or annulus." There is nothing in the Whiteside reference which refers to the combined outer regions of the backing portion 12 and surface portion 15 as an outer ring.

Responding to this argument the Examiner said in the Final Action:

The annular ring is integrally secured to the members. Given that the ring manifestly possesses an altogether different thickness and form, it is at least within a broadest reasonable interpretation for a person of ordinary skill in the art to consider it or characterize it as a ring."

That statement concedes that the Examiner has used Applicant's disclosure as a guide to reading the Whiteside reference. The Courts have repeatedly stated that his approach is wrong.

It is wrong to use patent in suit as guide through maze of prior art references, combining right references in right way so as to achieve results of claims in suit; Monday morning quarterbacking is quite improper when resolving the question of non-obviousness in a court of law.

Orthopedic Equipment Co., Inc. v. United States, 217 USPQ 193, 199; 702 F.2d 1005, 1012 (Fed. Cir. 1983).

Even if one skilled in the art would view a section of Whiteside's device as an annular ring that ring is integral to the backing element 12 and surface portion 15. This section is not "secured about said first member" as required by claim 15. It is only through impermissible hindsight that one can find an annular ring in the Whiteside device and when found that ring does not meet the requirements of claim 15. Because neither the annular ring nor the peripheral gap required by claim 15 are taught or suggested in the Whiteside patent, claim 15 is not anticipated or obvious from this reference.

Claim 22 requires the first and second members recited in claims 1, 8 and 15 together with "a porous coating containing at least one bone growth material and applied to at least a portion of at least one of said first member and said second member." Page 9, line 17, through page 10, line 4 of the specification teach that bone growth materials include hydroxyapatite,

human bone particles, bovine bone particles, ground coral and calcium sulfate. Although the Examiner rejected claim 22 under Section 102, the Office Action does not identify any structure in the Whiteside device that the Examiner regards as "a porous coating containing at least one bone growth material." Whiteside discloses "a porous layer such as sintered metal microbeads 14 to allow for tissue growth," (col. 2, lines 23-24). But, there is no teaching or suggestion of any material being contained in that layer. Because there is no bone growth material disclosed by Whiteside, the Examiner erred in rejecting claim 22 under Section 102.

In summary, all of the claims require a first member fabricated from a porous material, the first member having a rounded fixation surface and a flat surface opposite the rounded surface. Claim 15 as well as claims 16 through 21 which depend from claim 15 also require an annular ring secured about the first member. Claims 22 through 26 require a porous coating containing at least one bone growth material. None of these requirements are disclosed in the Whiteside reference. Therefore, the Examiner erred in rejecting the claims under Section 102 based upon Whiteside.

Claims 4, 11, 13, 16, 18 and 23 are Patentable
Under Section 103 Over Whiteside.

Only claims 4, 11, 13, 16, 18 and 23 were rejected under Section 103. The Examiner cited only the Whiteside reference as the basis for this rejection. Claim 16 requires that the annular ring be secured to the first member by an interference fit. As explained above Whiteside does not teach or suggest an annular ring secured to the first member.

Claims 4, 11 and 18 specify that the metal or ring is titanium. Claim 13, as well as claim 6, which is not addressed in the Final Office Action, requires that the second member be

fabricated from titanium or cobalt chrome. Claim 23 specifies particular material for the bone growth material required by claim 22.

The Examiner states that would have been obvious to form the Whiteside device of materials comprising hydroxyapatite, human bone particles, bovine bone particles, ground coral or calcium sulfate since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious choice. Office Action, page 3. The stated purpose of Whiteside's layer 14 is "to allow for tissue ingrowth." That can be and has been accomplished by a porous layer. Claim 22 requires both a porous layer and a material that promotes bone growth to be within that porous layer. Claim 23 specifies the material. There is no teaching of either a bone growth material or that bone growth should be promoted in the Whiteside reference. A reference does not support a conclusion of anticipation or obviousness where the reference does not teach all the limitations of a claim. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988). Accordingly, claims 22 and 23 are patentable over Whiteside.

The Examiner concedes that none of the limitations in claims 4, 11, 14, 16, 18 or 23 are disclosed by Whiteside. With respect to those claims which specify materials he relies upon *In re Leshin*, 125 USPQ 416 for the proposition that it is within the general skill of a worker to select a known material on the basis of its suitability for the intended use. While the proposition is correct, it can only be applied where there is a showing that it was known in the art that the selected materials are suitable for the intended use. Since Whiteside does not disclose any of the selected materials specified by claims 4, 11, 13, 16, 18 and 23, the reference does not disclose that such materials are suitable for use in a patella replacement device. The Examiner has cited

no other reference which discloses suitability of the claimed materials for the intended purpose.

Therefore, the Examiner improperly rejected the claims under Section 103.

All Claims are Patentable
Under Section 103.

For a rejection to be proper under Section 103 there must be something present in the teaching of the reference to suggest to one skilled in the art that the claimed invention would have been obvious.

"To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, it to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 312-313 (CAFC 1983), 721 F.2d 1540, 1553

For a claim to be obvious from a cited reference there must be some teaching or suggestion in the reference to modify the product to create the claimed invention. *In re Sernaker*, 702 F.2d 989, 995-996, 217 USPQ 1, 6 (Fed. Cir. 1983). Because the Whiteside reference does not teach or suggest a patella replacement device having the first member fabricated from a porous material as required by all pending claims, or the annular ring and peripheral gap required by claim 15, or the porous coating containing at least one bone growth material required by claim 22, the claims are patentable over this reference.

CONCLUSION

For the foregoing reasons the claims on appeal are patentable over the cited references.

Reversal of the rejections of the appealed claims are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lynn J. Alstadt", written in a cursive style.

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Date: December 28, 2006

Claims Appendix

Claims 1 through 26 are involved in the appeal and presented in their current form below:

1. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient, comprising:
 - a first member fabricated from a biocompatible porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with the porous metal allowing biological fixation to the patella region of the patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein; and
 - a second member fabricated from a biocompatible joint articulating material and having a top rounded surface and an opposing surface having an extending projection for coacting with said aperture to enable said first member to couple to said second member with said second member operative to allow articulation against the femoral area of said patient.
2. The patella replacement device according to claim 1 further comprising an annular ring having a central aperture for coupling to said flat surface of said first member and having a plurality of apertures about a periphery of said ring, the periphery surrounding and extending from a peripheral edge of said first member.
3. The patella replacement device according to claim 2 wherein said annular ring is fabricated from a biocompatible metal.
4. The patella replacement device according to claim 3 wherein said metal is titanium.

5. The patella replacement device according to claim 1 wherein said second member is fabricated from polyethylene.

6. The patella replacement device according to claim 1 wherein said second member is fabricated from titanium or cobalt chrome.

7. The patella replacement device according to claim 1 also comprising at least one annular collar attached to at least one of the first member and the second member.

8. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient, comprising:

a first member fabricated from a porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with said porous metal allowing biological fixation to said patella region of said patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein, and

a second member fabricated from a biocompatible material and having a top rounded surface and an opposing surface having an extending projection for coacting with said aperture in said first member and dimensional so that a peripheral gap is formed between said first and second member when said projection is inserted into said aperture, said gap enabling the accommodation of soft tissue.

9. The patella replacement device according to claim 8 further comprising:

an annular ring having a central aperture for coupling to said flat surface of said first member and having a plurality of apertures about a periphery of said ring, the periphery surrounding and extending from a peripheral edge of said first member.

10. The patella replacement device according to claim 9 wherein said annular ring is fabricated from a biocompatible metal.

11. The patella replacement device according to claim 10 wherein said metal is titanium.

12. The patella replacement device according to claim 8 wherein said second member is fabricated from polyethylene.

13. The patella replacement device according to claim 8 wherein said second member is fabricated from titanium or cobalt chrome.

14. The patella replacement device according to claim 8 wherein said relatively flat surface of said first member has three apertures, with said second member having three projections each adapted to coact with a respective associated one of said apertures.

15. A patella replacement device for use in repairing or replacing the destroyed natural patella comprising:

a first member fabricated from a porous metal material, said first member having a rounded fixation surface for implantation in the patella region of a patient, and a relatively flat surface opposite said rounded surface, said flat surface having at least one aperture therein;

an annular ring secured about said first member, said ring having a central aperture, an extending flange portion surrounding said first member and a plurality of apertures about a periphery thereof; and

a second member fabricated from a biocompatible material having a top round surface and an opposing surface having an extending projection for coacting with said aperture in said first member and dimensioned so that a peripheral gap is formed between said first and second members when said projection of said second member is inserted into said aperture of said first member.

16. The patella replacement device according to claim 15, wherein said annular ring is secured to said first member by an interference fit.

17. The patella replacement device according to claim 15 wherein said second member is fabricated from polyethylene.

18. The patella replacement device according to claim 15 wherein said annular ring is fabricated from titanium.

19. The patella replacement device according to claim 15 wherein said first member has three apertures on said flat surface.

20. The patella replacement device according to claim 19 wherein said second member has three projections each one operative to coact with an associated one of said three apertures of said first member.

21. The patella replacement device according to claim 15 wherein said porous metal material accommodates a bone cement placed in said at least one aperture.

22. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient comprising:

a first member fabricated from a biocompatible material and having a rounded fixation surface for implantation in the patella region of a patient, said first member having a relatively flat surface opposite said rounded surface and at least one aperture therein;

a second member fabricated from a biocompatible material and having a rounded surface and an opposing surface having an extending projection for coacting with said aperture to enable said first member to couple to said second member; and

a porous coating containing at least one bone growth material and applied to at least a portion of at least one of said first member and said second member.

23. The patella replacement device according to claim 22 wherein the at least one bone growth material is selected from the group consisting of hydroxyapatite, human bone particles, bovine bone particles, ground coral and calcium sulfate.

24. The patella replacement device according to claim 22 wherein at least one of said first member and said second member is fabricated from a material selected from the group consisting of biocompatible metals, biocompatible plastics and biocompatible ceramics.

25. The patella replacement device according to claim 22 wherein said first member is fabricated from a metal and said second member is fabricated from a plastic.

26. The patella replacement device according to claim 25 wherein said plastic is polyethylene and said metal is titanium or cobalt chrome.

Evidence Appendix

None.

Related Proceedings Appendix

None.